U.S.S.N. 09/975,672 Filed: October 10, 2001

RESPONSE TO OFFICE ACTION

## Remarks

Claims 26-34, 36-39, 43, 56, 59, and 61-66 are pending in the application.

## **Examiner Interview**

The undersigned thanks the Examiner for the cordial, brief telephonic interview on July 17, 2006. The undersigned understands from this interview that the Examiner may not have appreciated how the prior amendments altered the scope of the claims so as to distinguish over the cited prior art. The Examiner invited the undersigned to submit a written explanation further elucidating these distinctions. This response is therefore submitted.

## The Claims As Previously Amended Are Patentable Over the Cited Prior Art.

Claims 26-34, 36-39, 43, 56, 59, and 61-66 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent 6,123,861 to Santini et al. (hereinafter "Santini '861") in view of U.S. Patent 6,908,770 to McDevitt et al. (hereinafter "McDevitt") in further view of U.S. Patent 6,289,237 to Mickle et al. (hereinafter "Mickle"). The same claims were rejected as obvious over U.S. Patent 5,797,898 to Santini et al. (hereinafter "Santini '898") in view of McDevitt, in further view of Mickle. The same claims were rejected as obvious over U.S. Patent 5,989,445 to Wise et al. (hereinafter "Wise") in view of McDevitt, in further view of Mickle. These rejections are respectfully traversed.

## Applicants' Claimed Devices

Claim 26 is directed to a device having a reservoir in which is located a sensor that measures intrinsic electrical signals or loads on tissue structures *in vivo*. Importantly, the sensor is stored *inside* the reservoir until it is desired to expose the sensor to the environment outside of the reservoir. Similarly, claim 56 is directed to a system that includes a medical device having reservoirs that *contain* biosensors that measure intrinsic electrical signals or loads on tissue

U.S.S.N. 09/975,672

Filed: October 10, 2001

RESPONSE TO OFFICE ACTION

structures *in vivo*. Reservoir caps control exposure of the biosensor to the environment outside of the reservoirs. Claim 64 also requires that the biosensor be located *inside* each of at least two discrete reservoirs. Claim 64 further specifies that the implantable medical device include wireless means or hardwires for the transfer of biosensor data between the implantable medical device and a pacemaker or defibrillator. These features of the independent claims are not taught by the cited references, alone or in combination.

Applicants' Claims are Clearly Patentable Over the Santini Patents,

Alone or in Combination With McDevitt and Mickle.

Santini '861 and Santini '898 (collectively "the Santini Patents") emphatically do not teach "that the reservoir contents located in the reservoirs could include a sensor" as the Office Action mistakenly alleges. The Santini Patents viewed as a whole teach that the reservoir contents are *chemical molecules for release*, not sensors. The Examiner points to the disclosure at Cols. 8-11, but this disclosure merely describes using a biosensor to "send a signal to the microprocessor to activate one or more of the reservoirs." The Santini Patents mention "integrating a biosensor into the microchip to detect molecules in the surrounding fluid," but this cannot be construed, absent hindsight reconstruction *improperly viewed in light of the present disclosure*, as a suggestion to place a sensor <u>inside</u> the reservoir. Rather, this disclosure can only be viewed as teaching that the device may have a biosensor to detect when it is appropriate to release these chemical molecules. There is no mention or suggestion of putting this biosensor *inside* the reservoirs along with the drugs to be released. Moreover, such an interpretation would beg the question of how such an enclosed sensor could contact the surrounding fluid in order to detect molecules in the surrounding fluid to know when the reservoir should be opened. One of

U.S.S.N. 09/975,672

Filed: October 10, 2001

RESPONSE TO OFFICE ACTION

ordinary skill in the art therefore would not have read the Santini Patents as teaching the placement of a sensor inside a reservoir.

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Furthermore, the Santini Patents do not remotely suggest that the sensor is one that

measures intrinsic electrical signals or loads on tissue structures. The Santini Patents disclose

only that the sensor detects molecules in the surrounding fluid, and detecting molecules is

distinct from and not remotely suggestive of detecting electrical signals or loads on tissue

structures, as required by Applicants' claims 26 and 56.

Neither McDevitt nor Mickle supplement any of the foregoing absence of claim

elements. The claim elements missing from the Santini Patents are likewise missing from and

not suggested by McDevitt and Mickle.

Applicants' Claims are Clearly Patentable Over Wise, Alone

Or in Combination With McDevitt and Mickle.

Wise does not disclose or remotely suggest: (1) locating a sensor inside a reservoir for

controlled exposure, (2) the *claimed means* for selectively controlling reservoir contents

exposure described in the present application, or (3) disintegrating a reservoir cap to expose the

reservoir's contents. The Office Action's contentions to the contrary are simply unsupported by

a careful reading of Wise.

For instance, the Examiner's statement that Wise teaches "control of exposure may be by

a reservoir cap that may be opened by a cutting to expose the reservoir contents" is untenable.

First, Wise does not disclose a structure that is structurally and functionally equivalent to

Applicants' claimed "reservoir cap". Second, the "cutting" disclosed in Wise is dicing of the

wafer during a manufacturing process. This cutting is not remotely equivalent to disintegration,

U.S.S.N. 09/975,672 Filed: October 10, 2001

RESPONSE TO OFFICE ACTION

and even if cutting were construed to disintegrate, a wafer is more akin to Applicants'

"substrate", not the reservoir cap.

Furthermore, Wise does not remotely suggest a sensor that measures intrinsic electrical

signals or loads on tissue structures. Wise teaches only the use of flow sensors. Flow sensors

are not remotely suggestive of sensors that measure tissue loads or electrical signals.

Neither McDevitt nor Mickle supplement any of the foregoing absence of claim

elements. The claim elements missing from the Santini Patents are likewise missing from and

not suggested by McDevitt and Mickle.

In sum, the references fail to teach a device having reservoirs that contain a sensor for

measuring intrinsic electrical signals or loads on tissue structures in vivo and having Applicants'

disintegration means for controlling exposure of that sensor. At the time of Applicants'

invention, one of ordinary skill in the art would not have been led to take Wise or the Santini

Patents, combined either with McDevitt and Mickle, and then somehow be motivated to modify

the devices of those patents in the particular ways to derive the presently claimed devices.

Conclusions

Allowance of claims 26-34, 36-39, 43, 56, 59, and 61-66 is earnestly solicited.

Respectfully submitted,

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